

**BACTRIM DS- sulfamethoxazole tmp ds tablet**  
**Advanced Rx Pharmacy of Tennessee, LLC**

-----  
**Sulfamethoxazole and Trimethoprim 800mg/160mg tablets**

**Dosage and Administration Section**

**DOSAGE AND ADMINISTRATION**

Sulfamethoxazole and trimethoprim tablets are contraindicated in pediatric patients less than 2 months of age.

Urinary Tract Infections and Shigellosis in Adults and Pediatric Patients, and Acute Otitis Media in Children

Adults: The usual adult dosage in the treatment of urinary tract infections is 1 sulfamethoxazole and trimethoprim DS (double strength) tablet or 2 sulfamethoxazole and trimethoprim tablets every 12 hours for 10 to 14 days. An identical daily dosage is used for 5 days in the treatment of shigellosis.

Children: The recommended dose for children with urinary tract infections or acute otitis media is 40 mg/kg sulfamethoxazole and 8 mg/kg trimethoprim per 24 hours, given in two divided doses every 12 hours for 10 days. An identical daily dosage is used for 5 days in the treatment of shigellosis. The following table is a guideline for the attainment of this dosage:

Children 2 months of age or older:

Weight

Dose – every 12 hours

lb

kg

Tablets

22

10

-

44

20

1

66

30

1½

88

40

2 or 1 DS tablet

For Patients with Impaired Renal Function

When renal function is impaired, a reduced dosage should be employed using the following table:

Creatinine

Clearance (mL/min)

Recommended  
Dosage Regimen

Above 30

Usual standard regimen

15 to 30

½ the usual regimen

Below 15

Use not recommended

Acute Exacerbations of Chronic Bronchitis in Adults

The usual adult dosage in the treatment of acute exacerbations of chronic bronchitis is 1 sulfamethoxazole and trimethoprim double strength tablet, or 2 sulfamethoxazole and trimethoprim single strength tablets, every 12 hours for 14 days.

Pneumocystis Jiroveci Pneumonia

Treatment: Adults and Children

The recommended dosage for treatment of patients with documented *Pneumocystis jiroveci* pneumonia is 75 to 100 mg/kg sulfamethoxazole and 15 to 20 mg/kg trimethoprim per 24 hours given in equally divided doses every 6 hours for 14 to 21 days<sup>9</sup>. The following table is a guideline for the upper limit of this dosage:

Weight

Dose – every 6 hours

lb

kg

Tablets

18

8

-

35

16

1

53

24

1½

70

32

2 or 1 DS tablet

88

40

2½

106

48

3 or 1½ DS tablets

141

64

4 or 2 DS tablets

176

80

5 or 2½ DS tablets

For the lower limit dose (75 mg/kg sulfamethoxazole and 15 mg/kg trimethoprim per 24 hours) administer 75% of the dose in the above table.

### Prophylaxis

#### Adults

The recommended dosage for prophylaxis in adults is 1 sulfamethoxazole and trimethoprim DS (double strength) tablet daily<sup>10</sup>.

#### Children

For children, the recommended dose is 750 mg/m<sup>2</sup>/day sulfamethoxazole with 150 mg/m<sup>2</sup>/day trimethoprim given orally in equally divided doses twice a day, on 3 consecutive days per week.

The total daily dose should not exceed 1600 mg sulfamethoxazole and 320 mg trimethoprim<sup>11</sup>. The following table is a guideline for the attainment of this dosage in children:

#### Body Surface Area

Dose – every 12 hours

(m<sup>2</sup>)

Tablets

0.26

-

0.53

½

1.06

1

#### Traveler's Diarrhea in Adults

For the treatment of traveler's diarrhea, the usual adult dosage is 1 sulfamethoxazole and trimethoprim DS (double strength) tablet or 2 sulfamethoxazole and trimethoprim single strength tablets every 12 hours for 5 days.

## Indications and Usage Section

### INDICATIONS AND USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of sulfamethoxazole and trimethoprim tablets and other antibacterial drugs, sulfamethoxazole and

trimethoprim tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to empiric selection of therapy.

**Urinary Tract Infections:** For the treatment of urinary tract infections due to susceptible strains of the following organisms: *Escherichia coli*, *Klebsiella* species, *Enterobacter* species, *Morganella morganii*, *Proteus mirabilis* and *Proteus vulgaris*. It is recommended that initial episodes of uncomplicated urinary tract infections be treated with a single effective antibacterial agent rather than the combination.

**Acute Otitis Media:** For the treatment of acute otitis media in pediatric patients due to susceptible strains of *Streptococcus pneumoniae* or *Haemophilus influenzae* when in the judgment of the physician sulfamethoxazole and trimethoprim offers some advantage over the use of other antimicrobial agents. To date, there are limited data on the safety of repeated use of sulfamethoxazole and trimethoprim tablets in pediatric patients under two years of age. Sulfamethoxazole and trimethoprim tablets are not indicated for prophylactic or prolonged administration in otitis media at any age.

**Acute Exacerbations of Chronic Bronchitis in Adults:** For the treatment of acute exacerbations of chronic bronchitis due to susceptible strains of *Streptococcus pneumoniae* or *Haemophilus influenzae* when a physician deems that sulfamethoxazole and trimethoprim could offer some advantage over the use of a single antimicrobial agent.

**Shigellosis:** For the treatment of enteritis caused by susceptible strains of *Shigella flexneri* and *Shigella sonnei* when antibacterial therapy is indicated.

**Pneumocystis jiroveci Pneumonia:** For the treatment of documented *Pneumocystis jiroveci* pneumonia and for prophylaxis against *P. jiroveci* pneumonia in individuals who are immunosuppressed and considered to be at an increased risk of developing *P. jiroveci* pneumonia.

**Traveler's Diarrhea in Adults:** For the treatment of traveler's diarrhea due to susceptible strains of enterotoxigenic *E. coli*.

## Principal Display Panel

NDC 65162-272-10 <b>Sulfamethoxazole and Trimethoprim Tablets, USP</b> <b>800 mg/160 mg</b> <b>DOUBLE STRENGTH</b> 		<b>Each tablet contains:</b> Sulfamethoxazole, USP .....800 mg Trimethoprim, USP .....160 mg <b>Usual Dosage:</b> See package insert for full prescribing information. <b>DISPENSE IN TIGHT, LIGHT-RESISTANT CONTAINER.</b> <b>Storage:</b> Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Manufactured by: <b>Amneal Pharmaceuticals Pvt. Ltd.</b> <b>Oral Solid Dosage Unit</b> Ahmedabad 382213, INDIA Distributed by: <b>Amneal Pharmaceuticals LLC</b> Bridgewater, NJ 08807 Mfg. Lic. No. G/25/2137      Rev. 04-2019-00	 3 65162 27210 9 Non-Varnish Area (For Lot And Exp. Date) 38 x 64 mm
--	--	--	---

## BACTRIM DS

sulfamethoxazole tmp ds tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:80425-0001(NDC:65162-272)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>TRIMETHOPRIM</b> (UNII: AN164J8 Y0 X) (TRIMETHOPRIM - UNII:AN164J8 Y0 X)	TRIMETHOPRIM	160 mg
<b>SULFAMETHOXAZOLE</b> (UNII: JE4238 1TNV) (SULFAMETHOXAZOLE - UNII:JE4238 1TNV)	SULFAMETHOXAZOLE	800 mg

**Product Characteristics**

<b>Color</b>	white (White)	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL (Oval)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	IP;272
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:80425-0001-1	14 in 1 BOTTLE; Type 0: Not a Combination Product	09/13/2010	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA076899	09/13/2010	

**Labeler** - Advanced Rx Pharmacy of Tennessee, LLC (117023142)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0001)

Revised: 10/2020

Advanced Rx Pharmacy of Tennessee, LLC